UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRIAN VICENTE, **Plaintiff,** **v.** **JOHNSON & JOHNSON, DEPUY SYNTHES, UNIVERSITY HOSPITAL, RUTGERS UNIVERSITY, MARK ADAMS, JOHN DOES 1-100, ABC CORPORATIONS 1-100, and DEF COMPANIES/PARTNERSHIPS** **Defendants.**	Civ. No. 20-1584 (KM) (JBC) **OPINION**

KEVIN MCNULTY, U.S.D.J.:

This matter comes before the Court on the motion of Defendants DePuy Synthes Companies and DePuy Synthes Sales, Inc. (DE 6)[1] to dismiss Plaintiff Brian Vicente's Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). The action arises from personal injuries that plaintiff sustained as a result of an allegedly defective medical device that Defendants manufactured, designed, and distributed. Plaintiff asserts claims under the New Jersey Products Liability Act ("NJPLA"), N.J. Stat. Ann. § 2A:58-C *et seq.*, for design defect, manufacturing defect, and inadequate warnings. Plaintiff also asserts a claim for breach of express and implied warranty.

[1] Citations to the record will be abbreviated as follows. Citations to page numbers refer to the page numbers assigned through the Electronic Court Filing system, unless otherwise indicated:

"DE" = Docket entry number in this case.

"Compl." = Plaintiff's initial Complaint filed in state court (DE 1-1)

"Am. Compl." = Plaintiff's First Amended Complaint and Jury Demand (DE 5)

Plaintiff initiated this action in the Superior Court of New Jersey Law Division, Essex County against Johnson & Johnson, DePuy Synthes, University Hospital, Rutgers University, and Mark Adams, MD. DePuy Synthes Sales, Inc., ("DePuy") (inaccurately named as Depuy Synthes), removed the matter to the United States District Court for the District of New Jersey pursuant to 28 U.S.C. §§ 1332(a), 1441(a), and 1446 on the basis of this Court's diversity jurisdiction. (DE 1 at 1-2)

Plaintiff is a citizen of the State of New Jersey. (Compl. ¶1) On January 14, Plaintiff filed a voluntary dismissal of his claims against University Hospital, Rutgers University, and Mark Adams, M.D., all of whom were alleged to be citizens of New Jersey. (Compl. ¶¶4-6; DE 1-4 at 2) On February 13, 2020, Plaintiff filed a voluntary dismissal of Johnson & Johnson, also alleged to be a citizen of New Jersey. (Compl. ¶2; DE 1-5 at 2) DePuy then remained as the only defendant. The Complaint alleged that DePuy maintains offices in Pennsylvania. (Compl. ¶3) DePuy submits that its principal place of business is in Massachusetts, not Pennsylvania. (DE 1 ¶13) Either way, complete diversity of citizenship then existed between the parties and DePuy removed the matter to this Court on that basis on February 13, 2020. (DE 1)

After removal, Plaintiff filed an Amended Complaint (DE 5) naming DePuy and DePuy Synthes Companies (collectively "Defendants") as defendants, who, upon information and belief, are corporations existing under the laws the State of Massachusetts and whose principal place of business is in Massachusetts. (Am. Compl. ¶2) Plaintiff further alleges that "[t]he amount in controversy is more than $75,000.00 because plaintiff alleges he sustained severe personal injuries and resulting financial losses from a defective product." (Am. Compl. ¶ 3) Defendants now move (DE 6) to dismiss Plaintiff's Amended Complaint.

For the reasons set forth in this opinion, I will grant Defendants' motion to dismiss the Amended Complaint without prejudice.

I. Summary

The factual allegations of the Amended Complaint are accepted as true for purposes of this motion. On July 17, 2015, Plaintiff was in a motorcycle accident that resulted in fractures to his left femur, left metatarsal, and toes. (Am. Compl. ¶23) Three days later, Plaintiff underwent open reduction with internal fixation ("ORIF") procedures at University Hospital. (Am. Compl. ¶23) Plaintiff alleges that during this procedure, Defendant's LC-DCP SYSTEM[2] screws and plates were utilized. (Am. Compl. ¶25) Thereafter, "[i]t was necessary for plaintiff to undergo several procedures . . . related to open wound conditions and debridement." (Am. Compl. ¶26)

Plaintiff underwent one such procedure "on January 1, 2016, as a result of left distal femur fracture nonunion." (Am. Compl. ¶27) During the procedure, "it was noted that a 2.4 screw was loose, and it had to be removed." (Am. Compl. ¶27) On March 1, 2017, Plaintiff underwent another procedure "due to left distal demur nonunion with failure of the hardware." (Am. Compl. ¶28) It was noted during that procedure "that the heads of two of the screws were broken off the screws themselves" and "had to be located and removed." (Am. Compl. ¶29) "A 2.0 plate was separately located elsewhere around the femur, and it was also removed." (Am Compl. ¶30) Plaintiff alleges that the failure of Defendant's LC-DCP SYSTEM required the introduction of "new 4.5 screws in an effort to achieve stability in the femur." (Am. Compl. ¶32) After that procedure, "Plaintiff continued to experience extreme pain, deformity to the leg, and extreme instability." (Am. Compl. 33) Plaintiff alleges that the pain, deformity, and instability were caused by "nonunion due to hardware failure," which required Plaintiff to undergo a third procedure in April 2019. (Am. Compl. ¶¶34-35) During that procedure, Plaintiff "discovered, through his new orthopedic surgeon, that the hardware manufactured by defendants had completely failed, resulting in broken plate and screws." (Am. Compl. ¶35)

[2] "The LC-DCP SYSTEM stands for the defendants' 'Limited Contact Dynamic Compression Plate." (Am. Compl. ¶9)

As alleged in the Amended Complaint, Defendants are the manufacturers, marketers, and distributors of the LC-DCP SYSTEM screws and plates that were used during Plaintiff's procedures. (Am. Compl. ¶¶8, 25) Those screws and plates are "often utilized in surgical procedures involving the knee or leg, among other things." (Am. Compl. ¶8) Defendants "promoted the LC-DCP SYSTEM as a safe device for stabilization for the knee or leg, subsequent to a surgical procedure in which it was utilized." (Am. Compl. ¶10) Defendant promoted the system "as being technically sound and safe and, through publication, touted its technical improvements." (Am. Compl. ¶11) Plaintiff alleges that Defendants "touted" the following "improvements made in the plate component of the system." (Am. Compl. ¶12)

(a) The symmetrical shape of the plate holes was claimed to enable compression to be achieved on both directions.

(b) The ability of screws at up to 40 [degrees] to the perpendicular was claimed to permit an even wider range of applications.

(c) The new plate was claimed to be uniformly stiff.

(d) It was claimed that the screw head fit was maintained during bending as the plate holes deformed minimally during plate shaping.

(e) It was claimed that the shape of the holes was "regular" thus facilitating plate positioning.

(f) The plate was claimed to be equipped with a "double fracture" that spanned by the LC-DCP and lag screws through the plate.

(Am. Compl. ¶12) Further, the defendant "touted other aspects of the system such as its 'contouring' that contributed to satisfactory reduction and adequate stability." (Am. Compl. ¶13)

With respect to the LC-DCP SYSTEM's design, the Amended Complaint alleges that Defendants "claimed that the plate ensured uniform rigidity, hence a continuous curvature after bending." (Am. Compl. ¶14) Defendants "claimed use of a lag screw achieved 'full compression' or actually 'optimum compression,' in that it slid freely through the gliding hole." (Am. Compl. ¶15) Further, Defendants claimed the system "was fit for all applications, in that

due to its spring mechanism, all types of applications were possible: neutral position, compression position, buttress position and especially the positioning of inclined lag screws, through the plate." (Am. Compl. ¶16) Defendants also "touted the soundness of other components of the system," such as the buttress plate, the neutralization plate, and the protecting plate. (*Id.* ¶17)

Finally, the Amended Complaint alleges that Defendants placed the LC-DCP SYSTEM "into the stream of commerce with the actual or implied knowledge that the said product was defectively designed and/or manufactured; that it was likely to fail after its insertion in surgical procedures; and that the said product was not fit for its intended use or uses." (*Id.* ¶18). Further, Plaintiff alleges upon information and belief that "as of December 2016, the said product was reported to have been discontinued." (*Id.* ¶19) Additionally, Defendants "knew or had reason to believe of the propensity for the LC-DCP SYSTEM to fail since it was based on technology co-opted by them that often failed in the past and [was] recalled by the Food and Drug Administration" ("FDA"). (*Id.* ¶20) And "[f]rom 2005 to the present, a great number of medical devices manufactured by defendants and/or its affiliates was recalled by the FDA, many of which involved the led or knee." (*Id.* ¶21)

The Amended Complaint asserts four claims against the Defendants:

- Count One: Strict Liability – Design Defect
- Count Two: Strict Liability – Manufacturing Defect
- Count Three: Strict Liability – Inadequate Warning
- Count Four: Breach of Express and Implied Warranty.

(Am. Coml. ¶¶36-60) Counts One through Three are asserted pursuant to the NJPLA.

With respect to the Count One design defect claim, Plaintiff alleges that the LC-DCP SYSTEM

> was defective in its design when it left the hands of the defendants in that its design was flawed, thereby posing a serious risk that the device could fail after surgery, and thereby giving rise to pain and suffering, debilitation, and the need for revision surgeries to replace the device, with the attendant risk of complications from such

> further surgery. Yet, the defendants continued to market the aforesaid product.

(Am. Compl. ¶38) With respect to the Count Two manufacturing defect, Plaintiff alleges that the LC-DCP SYSTEM was defective when it left Defendants' hands because it "deviated from product specifications." (Am. Compl. ¶44) Regarding Count Three, Plaintiff alleges that the LC-DCP SYSTEM being "surgically implanted in [his] body was due to inadequate warning because the defendants' knew or should have known" about the aforementioned risks. (Am. Compl. ¶¶38, 50) Finally, with respect to Count Four, Plaintiff alleges that Defendants "expressly and implicitly warranted that the aforesaid product would be safe for insertion in patients' bodies." (Am. Compl. ¶56) However, the LC-DCP SYSTEM "did not conform to these express and implied representations in that its design was flawed." (Am. Compl. ¶57)

Defendants move to dismiss the Amended Complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. (DE 6-1 at 8-9) Defendants submit that Plaintiff's claims are subsumed within the PLA, which does not recognize implied warranty claims. (DE 6-1 at 7) Additionally, Defendants contend that

> Plaintiff does not plead his claims with the requisite specificity as he fails to identify: (1) a defect in the design of the device or in the manufacture of the device that his doctor implanted; (2) the inadequacies in the warning that companied the device; and (3) the language of the warranty that purportedly accompanied the device.

(DE 6-1 at 7)

II. Discussion

a. Legal standard

Federal Rule of Civil Procedure 8(a) does not require that a complaint contain detailed factual allegations. Nevertheless, "a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see Phillips v.*

Cnty. of Allegheny, 515 F.3d 224, 232 (3d Cir. 2008) (Rule 8 "requires a 'showing' rather than a blanket assertion of an entitlement to relief." (citation omitted)). Thus, the complaint's factual allegations must be sufficient to raise a plaintiff's right to relief above a speculative level, so that a claim is "plausible on its face." *Twombly*, 550 U.S. at 570; *see also West Run Student Hous. Assocs., LLC v. Huntington Nat. Bank*, 712 F.3d 165, 169 (3d Cir. 2013).

That facial-plausibility standard is met "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). While "[t]he plausibility standard is not akin to a 'probability requirement' . . . it asks for more than a sheer possibility." *Id.*

Rule 12(b)(6) provides for the dismissal of a complaint if it fails to state a claim upon which relief can be granted. The defendant, as the moving party, bears the burden of showing that no claim has been stated. *Animal Science Products, Inc. v. China Minmetals Corp.*, 654 F.3d 462, 469 n.9 (3d Cir. 2011). For the purposes of a motion to dismiss, the facts alleged in the complaint are accepted as true and all reasonable inferences are drawn in favor of the plaintiff. *New Jersey Carpenters & the Trustees Thereof v. Tishman Const. Corp. of New Jersey*, 760 F.3d 297, 302 (3d Cir. 2014).

When deciding a motion to dismiss, a court typically does not consider matters outside the pleadings. However, a court may consider documents that are "integral to or explicitly relied upon in the complaint" or any "undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document[.]" *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999) (emphasis and citations omitted); *see In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 n.7 (3d Cir. 2016); *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014). In that regard, courts may consider matters of public record and exhibits attached to the complaint. *Schmidt*, 770 F.3d at 249 ("To decide a motion to

dismiss, courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record"); *Arcand v. Brother Int'l Corp.*, 673 F. Supp. 2d 282, 292 (D.N.J. 2009) (court may consider documents referenced in complaint that are essential to plaintiff's claim). Reliance on these types of documents does not convert a motion to dismiss into a motion for summary judgment. "When a complaint relies on a document . . . the plaintiff obviously is on notice of the contents the document, and the need for a chance to refute evidence is greatly diminished." *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196-97 (3d Cir. 1993).

b. New Jersey's Product Liability Act

The NJPLA "recognizes three claims: design defect, manufacturing defect, or failure to warn." *Mendez v. Shah*, 94 F. Supp. 3d 633, 637 (D.N.J. 2015) The Act provides:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J. Stat. Ann. § 2A:58C-2. Under the Act, a product liability action "means any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J. Stat. Ann. § 2A:58C-1(b)(3). Harm is also defined:

> "Harm" means (a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.

N.J. Stat. Ann. § 2A:58C-1(b)(2).

As a threshold issue, Defendants submit that Plaintiff's claim for breach of implied warranty is subsumed by the PLA. (DE 6-1 at 9) I will address this argument before further analyzing the sufficiency of Plaintiff's pleadings.

As the New Jersey Supreme Court has noted, "[t]he language chosen by the Legislature in enacting the [NJ]PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *In re Lead Paint Litig.*, 924 A.2d 484, 503 (N.J. 2007) (citing N.J. Stat. Ann § 2A:58C-1(b)(3)). Indeed, with the passage of the NJPLA, "there came to be one unified, statutorily defined theory of recovery for harm caused by a product." *Id.* (internal quotation marks omitted) (quoting William A. Dreier et al., *New Jersey Product Liability & Toxic Torts Law* § 1:2-1 (2007)). In enacting the NJPLA, the New Jersey Legislature intended "to limit the liability of manufacturers" and "balance[] the interests of the public and the individual with a view towards economic reality." *Sinclair v. Merck & Co., Inc.*, 948 A.2d 587, 593 (N.J. 2008) (alteration in original) (internal quotation marks omitted) (quoting *Zaza v. Marquess & Nell, Inc.*, 675 A.2d 620, 627 (N.J. 1996)). As the Third Circuit has explained, the NJPLA "effectively creates an exclusive statutory cause of action for claims falling within its purview" and "generally subsumes common law product liability claims, thus establishing itself as the sole basis of relief under New Jersey law available to consumers injured by a defective product." *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991); *see also Hindermyer v. B. Braun Medical Inc.*, 419 F. Supp. 3d 809, 817 (D.N.J. 2019).

In considering "whether the NJPLA subsumes a particular claim, the court must ascertain the type of harm that a plaintiff is alleging; namely, whether the harm involves property damage or bodily injury caused by the alleged defective product, or whether the harm was solely to the product, itself." *Hindermyer*, 419 F. Supp. 3d at 818. Thus, "courts do not simply determine whether or not the victim's injury was literally 'caused by a product.'" *Id.* (internal quotation marks omitted) (quoting *New Hope Pipe Liners,*

LLC. V. Composites One, LCC, No. 09-3222, 2009 WL 4284644, at *2 (D.N.J. Nov. 30, 2009)). Instead, "courts tend to look at the essence of the claims and decide whether or not the plaintiff is disguising what would traditionally be considered a products liability claim as an alternative cause of action." *Id.* (internal quotation marks omitted) (quoting *New Hope Pipe Liners*, 2009 WL 4284644 at *2).

Because of the NJPLA's broad scope, "New Jersey federal and state courts have consistently dismissed product liability-related claims based on common law theories when at the heart of those theories is the potential 'harm caused by a product.'" *Id.* (citing *Port Auth. of N.Y. & N.J. v. Arcadian Corp.*, 189 F.3d 305, 313 (3d Cir. 1999) (dismissing negligence claim, because "under New Jersey law negligence is no longer viable as a separate claim for harm caused by a product"); *Thomas v. Ford Motor Co.*, 70 F. Supp. 2d 521, 528-29 (D.N.J. 1999) (dismissing common-law claim for negligent manufacture); *Reiff v. Convergent Techs.*, 957 F. Supp. 573, 583 (D.N.J. 1997) (dismissing negligence and implied breach of warranty claims); *McWilliams v. Yamaha Motor Corp. USA*, 780 F. Supp. 251, 262 (D.N.J. 1991) (dismissing negligence and breach of implied warranty claims), *aff'd in part, rev'd in part on other grounds*, 987 F.2d 200 (3d Cir. 1993); *Green v. GMC*, 709 A.2d 205, 209 (App. Div. 1998) (stating that "causes of action for negligence, strict liability and implied warranty have been consolidated into a single product liability cause of action" under the NJPLA)). *See also New Hope Pipe Liners*, 2009 WL 4282644 at *2 ("[I]f the facts of a case suggest that the claim is about defective manufacture, flawed product design, or failure to give an adequate warning, then the PLA governs and the other claims are subsumed.").

In *Hindermyer*, a court in this District recently held, *inter alia*, that the plaintiff's implied warranty claim was subsumed by the PLA because the factual allegations in the Complaint – that the plaintiff was injured as a result of using the VenaTech Filter and that she suffered physical pain from the implantation of that medical device – demonstrate that the action arose from

the alleged personal injuries the plaintiff sustained as a result of an allegedly defective product. 419 F. Supp. 3d at 819. Here, in Count Four, Plaintiff alleges that Defendants "expressly and implicitly warranted that the aforesaid product would be safe for insertion in patients' bodies" but that the "product did not conform" to those warranties "in that its design was flawed thereby posing a serious risk that the device could fail after surgery, and thereby giving rise to pain and suffering, debilitation, and the need for revision surgeries." (Am. Compl. ¶¶56-57) In other words, Plaintiff maintains the product was flawed and that flaw caused "pain and suffering," among other injuries. Therefore, I find Plaintiff's implied warranty claim is subsumed by the NJPLA because the essence of the claim is one for personal injuries from a defective product. *See Hindermyer*, 419 F. Supp. 3d at 819.

Plaintiff argues that his implied warranty claim is not subsumed because the claims set forth in Count Four "do[] not involve design or warning defects." (DE 7 at 27) Instead, Plaintiff contends that he was harmed by affirmative misrepresentations about the safety of the product at issue. (DE 7 at 27) However, the test is not whether a plaintiff literally alleged a design or manufacturing defect or alleged a failure to warn. Instead, a court must "look at the essence of the claims and decide whether or not the plaintiff is disguising what would traditionally be considered a products liability claim as an alternative cause of action." *Hindermyer*, 419 F. Supp. 3d at 818 (internal quotation marks omitted) (quoting *New Hope Pipe Liners*, 2009 WL 4284644 at *2). In Count Four, the Amended Complaint alleges that the LC-DCP system did not conform to the Defendants express and implied warranties "*in that its design was flawed*." (Am. Compl. ¶57) (emphasis added). Thus, Plaintiff attempts to repackage a design defect claim as one for breach of implied warranty. For that reason, his claim is subsumed by the NJPLA. And the case law Plaintiff relies upon confirms rather than dispels that conclusion.

Plaintiff relies on four cases for the proposition that a claim based on affirmative misrepresentations about the safety of a product is not subsumed

by the NJPLA. (*See* DE 7 at 27) In *Wendling v. Pfizer, Inc.*, the plaintiffs alleged that the "advertisement for defendant's veterinary product, Strongid C, was false and misleading because it stated that it would 'prevent and control parasites every day,' but it did not prevent or control tapeworms, a type of parasite, that infested and eventually killed their horse." No. A-1807-06T1, 2008 WL 833549, at *1 (N.J. Super. Ct. App. Div. Mar. 31, 2008). The Superior Court of New Jersey, Appellate Division, held that the plaintiffs' negligent misrepresentation claim was not subsumed by the PLA because the plaintiffs did not allege product defect or that the product was not reasonably fit for its intended use due to inadequate warnings. *Id.* at *8. "Instead, they alleged that there was a misleading, false or materially deficient product advertisement. In other words, it was not the product itself that caused the harm, but allegedly its misleading promotion." *Id.* Here, again, Plaintiff alleges that the product did not conform to Defendants' warranties because the "design was flawed" "thereby giving rise to pain and suffering." (Am Compl. ¶57) *Wendling* is not analogous because the plaintiffs there did not allege that they were harmed by a flawed product; instead, they allegedly used a product based on the representations that it would prevent a certain type of parasite that it did not in fact prevent.

In *Nafar v. Hollywood Tanning Systems, Inc.*, the court held that the plaintiff's "claims based on the allegation that Defendant knew of dangers associated with its tanning beds, and failed to disclose them, must be considered 'failure to warn' claims," and, as such were subsumed under the NJPLA. No. 06-3826, 2010 WL 2674482, at *11 (D.N.J. June 30, 2010). The only claims that were not subsumed were the plaintiff's "claims premised upon misleading advertisements and/or representations made by employees at Defendant's franchises" that "customers 'will look terrific,' and that tanning will help to clear acne, and has benefits with respect to psoriasis, body weight, stress, and seasonal affective disorder." 2010 WL 2674482 at *8, *11. Here, Plaintiff alleges no specific misleading representations or advertisements made

by Defendants. Instead, Plaintiff alleges that the implied warranty that the product was safe was breached because the design was flawed and caused injury. (Am. Compl. ¶57)

In *Gupta v. Asha Enterprises, L.L.C.*, the plaintiffs asserted claims of negligence, negligent infliction of emotional distress, consumer fraud, products liability, and breach of express and implied warranties arising when the defendant restaurant "filled their order for vegetarian samosas with meat-filled samosas causing spiritual injuries resulting in damages." 27 A.3d 953, 956 (N.J. Super. Ct. App. Div. 2011) The Appellate Division held that the NJPLA was inapplicable to the plaintiffs' claims because those claims were "not related to a defect in the samosas themselves, which were safe, edible and fit for human consumption, but rather to allegations that they were supplied the wrong product." *Id.* at 958. By analogy, Plaintiff Vicente does not allege that the wrong screws or plates were used; instead, he contends that those screws and plates were flawed. (Am. Compl. ¶57) Therefore, *Gupta* does not help him.

Finally, Plaintiff relies on *New Hope Pipe Liners*. There, the court dismissed the plaintiff's implied warranty claim because it was "in essence the same" as the plaintiff's product liability claims. Both, the court found, asserted that the product was not reasonably fit or suitable for its intended purpose. 2009 WL 4282644 at *4. The court explained:

> Both claims center on the notion that the 3141 Resin did not perform as well as such a product is generally supposed to perform. These claims do not concern the Defendants' representations but rather the question of whether the 3141 Resin measured up to common expectations. These are classic products liability-type claims, and as such, the [NJ]PLA is the sole cause of action.

Id.

Similarly, here, Plaintiff's implied warranty claim is premised on the LC-DCP SYSTEM allegedly not performing as it should, causing the plaintiff injury. To say that Defendants did not disclose that deficiency does not fundamentally change the nature of the claim. Such a "classic products liability-type claim[]" is subsumed by the NJPLA. *See id.*

Because Plaintiff's implied warranty claim is subsumed by the NJPLA, it must be dismissed. However, the NJPLA recognizes claims for breach of express warranty, which will be addressed later in this opinion. *See* N.J. Stat. Ann. § 2A:58C-1(b)(3)

c. Design Defect

The standard for liability in each NJPLA cause of action "is that the product 'was not reasonably fit, suitable or safe for its intended purpose.'" *Mendez*, 94 F. Supp. 3d at 637 (quoting *Cornett v. Johnson & Johnson*, 998 A.2d 543, 562 (N.J. Super. Ct. App. Div. 2010)); *Hindermyer*, 419 F. Supp. 3d at 823 (quoting same). "To prove a defect, 'a plaintiff must be able to show that: (1) the product was defective; (2) the defect existed when product left the hands of the defendant; and (3) the defect caused the injury to a reasonably foreseeable user.' " *Mendez*, 94 F. Supp. 3d at 637 (quoting *McGarvey v. G.I. Joe Septic Service, Inc.*, 679 A.2d 733, 740 (N.J. Super. Ct. App. Div. 1996).

To establish a *prima facie* design defect claim, a plaintiff must allege an actionable defect: generally, "the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm without substantially impairing the reasonably anticipated or intended function of the product." *Hindermyer*, 419 F. Supp. 3d at 823-24 (citing *Cavanagh v. Skil Corp.*, 751 A.2d 518, 520 (N.J. 2000)); *Lewis v. Am. Cyanamid Co.*, 715 A.2d 967, 980 (N.J.1998) ("In a design-defect case . . . [a] plaintiff must prove either that the product's risks outweighed its utility or that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm."). At the pleading stage, courts in this District have observed that while "there is no 'per se rule that Plaintiffs must, under all circumstances, provide a reasonable alternative design,' a plaintiff must plead either that the product's risk [of harm] outweighs its [utility], or that an alternate design exists, in order to state a claim for a design defect under the' NJPLA." *Id.* (alterations in original) (quoting *Mendez v. Shah*, 28 F. Supp. 3d 282, 297-98 (D.N.J. 2014) ["*Mendez I*"]). Indeed, "the critical issue in design-

defect cases is the reasonableness of the manufacturer in marketing that design." *Zaza*, 675 A.2d at 631. *See also Sich v. Pfizer Pharm.*, No. 117-02828, 2017 WL 4407930, at *2 (D.N.J. Oct. 4, 2017) ("The plaintiff must demonstrate that the 'product [was] manufactured as intended but the design render[ed] the product unsafe.'" (alterations in original) (quoting *Pollander v. Desimone BMW of Mt. Laurel, Ltd.*, No. A-3204-10T3, 2012 WL 127563, at *3 (N.J. Super. Ct. App. Div. Jan. 18, 2012)).

Numerous courts in this District have dismissed a plaintiff's design defect claim under the NJPLA at the pleading stage for failing to allege a reasonable alternative design or failing to allege that the risk outweighed the product's utility. *See e.g. Hindermyer*, 419 F. Supp. 3d at 825 (dismissing a design defect claim because the plaintiff did not plead the existence of an alternative design); *Mendez I*, 28 F. Supp. 3d at 298 (dismissing a design defect claim because the plaintiff failed to present a risk-utility analysis) *Greisberg v. Boston Scientific Corp.*, No. 19-12646, 2020 WL 278648, at *5 (D.N.J. Jan. 17, 2020) (dismissing a design defect claim because the plaintiff did not provide either a risk-utility analysis or plead the existence of an alternative design); *Sich*, 2017 WL 4407930, at *2 (dismissing a design defect claim because the plaintiffs "simply alleged injury.")

Here, however, Plaintiff submits that he was not required to plead an alternative design or engage in a risk-utility analysis because a design defect may also be established by the "consumer expectations" test. (DE 7 at 18) Defendants reply that the consumer expectation test is not applicable because the device at issue is complex and outside the experience of an ordinary consumer. (DE 9 at 7-8)

"A court may at times apply the consumer expectations test to determine whether a product was defectively designed." *McAlonan v. Tracy*, No. A-6034-07T2, 2011 WL 6125, at *6 (N.J. Super. Ct. App. Div. Mar. 16, 2010) (quoting *O'Brien v. Muskin Corp.*, 463 A.2d 298, 304 (N.J. 1983)). That test applies when "it is self-evident that the product is not reasonably suitable and safe and fails

to perform, contrary to the user's reasonable expectation that it would 'safely do the jobs for which it was built.'" *Id.* (internal quotation marks omitted) (quoting *Suter v. San Angelo Foundry & Mach. Co*, 406 A.2d 140, 150 (N.J. 1979)). Thus, the consumer expectation test is applicable only where the product design is *self-evidently* defective. *Mettinger v. W.W. Lowensten, Inc.*, 678 A.2d 1115, 1123 (N.J. Super. Ct. App. Div. 1996) ("*Suter* teaches that the 'consumer expectations' test is applicable only where the product, 'like a bicycle whose brakes [do] not hold because of an improper design,' is 'self-evident[ly] . . . not reasonably suitable and safe and fails to perform.'") (alterations in original) (quoting *Suter* 406 A.2d at 150). In turn, "[t]he design of a product is "self-evidently" defective when there are no relevant considerations which make the hazard inherent in the product or reasonably necessary to its functioning." *Id.* In such circumstances, the risk-utility analysis is unnecessary and "[t]he only material question is whether the product has been designed so as to pose a hazard that is contrary to the user's reasonable expectations." *Id.*

In *McAlonan*, the Appellate Division declined to apply the consumer expectation test to the plaintiff's claims involving an allegedly defective air bag system. 2011 WL 6125 at *6. The court reasoned that there was "no evidence to indicate that the Echo's airbag system was self-evidently defective and that the product was unsafe for any foreseeable use." *Id.* Instead, expert testimony revealed that "it was unlikely an ordinary consumer would know what to expect or how safely an airbag system could be made to perform in all foreseeable situations, including the type of collision at issue" in that case. *Id.* In *Mettinger*, the Appellate Division held that the jury was properly instructed on the consumer expectation test where the plaintiff's was injured by "the rapidly rotating blade of a Globe model 500 slicing machine used to slice cheeses and meats" with a removed blade guard. 678 A.2d at 1118-19, 1123. The court reasoned that "the evidence did not suggest any consideration of feasibility, cost or functionality which might tend to justify the omission of a blade guard interlock." *Id.* at 1123. Thus, "[t]he only relevant question left for the jury was

whether the Globe Model 500 slicing machine was so hazardous that it was contrary to a user's reasonable expectations." *Id.* The court also noted that the circumstances met the instruction in *O'Brien* that the consumer expectation test be applied "only where the product is unsafe in any foreseeable use." *Id.* (reasoning that "a delicatessen slicing machine cannot be used satisfactorily without frequent and thorough cleaning of its blade.").

Plaintiffs submit that the product defects alleged here "are not complex because they involve the breaking of a plate and screws" which are "within the knowledge and expectations of the ordinary consumer." (DE 7 at 19) Defendants contend that "[d]evices designed for use in the human body for their therapeutic effect are complex and subject to many known risk factors that are not apparent to the average consumer." (DE 9 at 8) Defendants note that while most medical practitioners know that delayed union or nonunion of a fracture "is a common risk associated with orthopedic devices . . . it is not common knowledge for patients or consumers." (DE 9 at 8)

Defendants point to the following warning on DePuy's package insert: "**These devices can break when subjected to the increased loading associated with delayed union or nonunion.** Internal fixation appliances are load sharing devices which hold a fracture in alignment until healing occurs. If healing delayed, or does not occur, the implant could eventually break due to metal fatigue." (DE 9-1 at 2) Defendants submit that the Court can take judicial notice of that warning because the package insert was included as part of DePuy's 510K submissions and facts about FDA approvals are ripe for judicial notice. (DE 9 at 8 n.2 (citing *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 592 n.2 (D.N.J. 2015 ("[F]acts about the FDA approvals . . . are also matters of public record, appropriate for judicial notice.")) In *Clements*, the court took judicial notice of regulatory facts regarding the FDA approval of the medical device in issue even though the plaintiff did not plead such facts in her Complaint. 111 F. Supp. 3d at 592 n.2. However, in *Sweeny v. Alcon laboratories, Inc.*, the court refused to take judicial notice of the contents of the

package inserts or accept that material "introduced by way of opposition brief." No. 16-4860, 2019 WL 1320671, at *7-8 (D.N.J. Mar. 14, 2018). Irrespective of the package inserts, however, I would find that the soundness of the medical device at issue here is not within the ken of the average consumer.

As alleged in the Amended Complaint, the LC-DCP SYSTEM involves the insertion of plates and screws that are used in surgical procedures involving the knee or leg. (Am. Compl. ¶8) As with the air bags in *McAlonan,* I find it is unlikely an ordinary consumer would know how safely such system "could be made to perform in all foreseeable situations." *See* 2011 WL 6125 at *6; *see also Parvez & Razia Yazdani v. BMW of N. Am.*, LLC, 188 F. Supp. 3d 486, 493 (E.D. Pa. 2016) ("The consumer expectations test is inappropriate because the fire hazard posed by the motorcycle's alleged defective design is beyond the everyday understanding of the ordinary consumer."). An average consumer would not know how long surgical screws maintain their structure after nonunion of a fracture. This is far from a lay person's common experience of, say, joining two pieces of wood with plates and screws. The system is not akin to the bicycle whose brakes do not hold, the hypothetical "common knowledge" case posed in *Suter*. *See* 406 A.2d at 150.

The "consumer expectation" shortcut is unavailable. It is not enough to allege that an injury should not have happened, so there must have been a design defect. Because Plaintiff did not plead a reasonable alternative design or risk-utility analysis, his design defect claim is dismissed.

d. Manufacturing Defect

In a manufacturing defect case, "a plaintiff must prove that the product was defective, that the defect existed when the product left the manufacturer's control, and that the defect proximately caused injuries to the plaintiff, a reasonably foreseeable or intended user." *Myrlak v. Port Auth. of New York & New Jersey,* 723 A.2d 45, 52 (1999) "[A] manufacturing defect exists if a product 'deviated from the design specification, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured

to the same manufacturing specifications or formulae.'" *Hindermyer*, 419 F. Supp. 2d. at 824 (quoting N.J. Stat. Ann. § 2A:58C-1(a)). In determining whether a product contains a manufacturing defect, "the 'product may be measured against the same product as manufactured according to the manufacturer's standards.'" *Id.* (quoting *Mendez I*, 28 F. Supp. 3d at 298). If the product in question fails to conform to those standards, "or other units of the same kind," then there exists a manufacturing defect. *Id.* (internal quotation marks omitted) (quoting *Mendez I*, 28 F. Supp. 3d at 298).

Under New Jersey law, the plaintiff need not prove the nature or etiology of the manufacturing defect with scientific precision. *Id.* "Rather, because the evidence of a flaw in the manufacturing process is uniquely within the knowledge and control of the manufacturer, '[p]roof that a product is not fit for its intended purposes 'requires only proof . . . that 'something was wrong' with the product.'" *Id.* (alterations in original) (quoting *Myrlak*, 723 A.2d at 52). However, "[t]he mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect." *Myrlak*, 723 A.2d at 52.

Here, Defendants submit that the "Amended Complaint is deficient because it fails to identify the defect in the LC-DCP System that [Plaintiff's] doctor implanted" and "fails to allege any facts about the supposed manufacturing defect(s) that caused the device to fail." (DE 6-1 at 14) I agree and will dismiss the manufacturing defect claim on that basis. *See, e.g.*, *Hindermyer*, 419 F. Supp. 3d at 827 (dismissing manufacturing defect claim on the basis of pleading deficiencies because the plaintiff failed to identify "even in general terms, a particular error or mishap in the manufacturing process that caused her VenaTech Filter to deviate from Defendants' own standards, nor [did] she contend that her device failed to conform to other identical units."); *Dingler v. Am. Med. Sys., Inc.*, No. 19-8672, 2019 WL 6310057, at *2 (D.N.J. Nov. 25, 2019) (dismissing manufacturing defect claim because the plaintiff alleged only that the products "caused adverse reactions and did not perform

their intended purposes" but did "not allege any standard—be it a design specification, formulae, or performance of the manufacturer, or an identical unit manufactured to the same manufacturing specifications or formulae—from which the Products deviated."); *Sich*, 2017 WL 4407930, at *3 (dismissing manufacturing defect clam because the plaintiff failed to explain "how the drug differed from the requisite standard or how it was allegedly defective."); *Delaney v. Stryker Orthopaedics*, No. 08-3210, 2009 WL 564243, at *6 (D.N.J. Mar. 5, 2009)(dismissing manufacturing defect claim because the complaint did not specify the way in which the product in issue deviated from the manufacturing process approved by the FDA and asserted no facts "to support the bald allegation" that the device fractured because of a manufacturing defect).

Here, again, the Plaintiff attempts to avail himself of a shortcut or exception. Under the "intermediate product defect test," he asserts, there is sufficient circumstantial evidence to lead a reasonable fact finder to infer that the product was defective in its manufacture." (DE 7 at 15) In *Myrlak*, the New Jersey Supreme Court held "that the traditional negligence doctrine of *res ipsa loquitur* generally is not applicable in a strict products liability case" but adopted "the 'intermediate product defect test' established in Section 3 of the *Restatement (Third) of Torts: Products Liability* as the more appropriate jury instruction in cases that do not involve a shifting of the burden of persuasion." 723 A.2d at 48. Under that test,

> [i]t may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff:
>
> (a) was of a kind that ordinarily occurs as a result of a product defect; and
>
> (b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.

Myrlak, 723 A.2d at 55 (quoting *Restatement (Third) of Torts* § 3 (1997)).

Here, the Amended Complaint makes no allegation that the injury Plaintiff suffered was the kind that ordinarily occurs as a result of a defective product or that the incident was not solely the result of causes other than the product defect.

In briefing, Plaintiff points to the allegation in the Amended Complaint about the specific representations Defendants made about the reliability and safety of the product. (DE 7 at 15) According to Plaintiff, those claims were "unfounded" because the device utilized during his surgery "utterly failed." (DE 7 at 15-16) It appears Plaintiff is arguing that the product had a manufacturing defect because it deviated from Defendants' safety claims. Such contentions fall short, or perhaps somewhere to the side, of the intermediate product defect test. Because Plaintiff failed to allege any of the elements under that test, I find it inapplicable. The manufacturing defect claim is dismissed.

e. Failure to Warn

"A manufacturer is liable for harm caused by a failure to warn if the product does not contain an adequate warning or instruction." *Hindermyer*, 419 F. Supp. 3d at 824 (alteration in original) (internal quotation marks omitted) (quoting *Sich*, 2017 WL 4407930, at *3). An adequate warning is defined by statute as "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product." N.J.S.A. § 2A:58C-4. "A product warning or instruction that does not comport with this statutory requirement is defective." *Banner v. Hoffmann-La Roche Inc.*, 891 A.2d 1229, 1236 (N.J. Super. Ct. App. Div. 2006)

Here, the Amended Complaint contains no allegations about the warnings associated with the product at issue or how such warnings are inadequate. With respect to Plaintiff's inadequate warning claim, the Amended Complaint states only this: "The aforesaid product surgically implanted in plaintiff's body was due to inadequate warning because the defendants' knew or should have known there existed a serious risk that the device could fail after surgery, thereby giving rise to pain and suffering, debilitation, and the

need for revision surgeries." (Am. Compl. ¶50) Such a blanket assertion of entitlement to relief does not pass the plausibility test. *See Twombly*, 550 U.S. at 570.

Further, the NJPLA "incorporates the 'learned intermediary doctrine' under which a pharmaceutical manufacturer generally fulfills its duty to warn the ultimate user of its prescription drug . . . when it supplies physicians with adequate information about a drug's dangerous propensities." *Banner*, 891 A.2d at 1236. The only exception to that doctrine "arises when a pharmaceutical company has advertised its drug directly to the consuming public." *Id.* (citing *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245 (N.J. 1999)). In briefing, Plaintiff submits that "most if not all of the assertions made by DePuy were directed at the consumer." (DE 7 at 22) However, the Amended Complaint contains no such allegation.

Additionally, the NJPLA provides a rebuttable presumption that warnings or instructions approved by the FDA are adequate:

> If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate.

N.J. Stat. Ann. § 2A:58C-4. "For all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims." *Perez*, 734 A.2d at 1259. Plaintiff alleged no facts to rebut the presumption of reasonableness and alleged no facts regarding deliberate concealment or nondisclosure of harmful effects.

For all of these reasons, Plaintiff's failure to warn claim is dismissed.

f. Breach of Express Warranty

An express warranty by a seller is created as follows:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the

> bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

N.J. Stat. Ann. § 12A:2-313(1). "[A]n affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." N.J. Stat. Ann. § 12A:2-313 (2).

Under New Jersey law, to state a claim for breach of express warranty, Plaintiff "must properly allege: (1) that Defendant[s] made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 706 (D.N.J. 2011) Courts in this District have dismissed express warranty claims where the pleading fails to allege the actual language or source of any alleged warranty. *Id.* ("Since Plaintiffs' allegations are simply "bald assertions" that fail to identify specific affirmations or promises by Defendants, the claim as pleaded cannot survive a motion to dismiss."); *Simmons v. Stryker Corp.*, No. 08–3451, 2008 WL 4936982, at *2, (D.N.J. Nov. 17, 2008) ("Plaintiff's breach of warranty claim is devoid of any "factual matter" to support the existence of an express warranty. Rather, there is simply a conclusory recitation of the elements of the claim. Plaintiff has alleged no facts to suggest that an express warranty existed."); *Parker v. Howmedica Osteonics Corp.*, No. 07–2400, 2008 WL 141628, at *6, (D.N.J. Jan. 14, 2008) (general references to "press releases" and "assurances of safety," as opposed to specific statements, cannot survive a motion to dismiss).

Here, the Amended Complaint contains no allegation identifying the language or source of any alleged express warranty. Therefore, Plaintiff's express warranty claim must fail.

Plaintiff's opposition brief does not address Defendants' argument the Amended Complaint fails to allege sufficient facts to support the express warranty claim. Thus, Plaintiff is deemed to have waived that point. *See Hollister v. U.S. Postal Serv.*, 142 F. App'x 576, 577 (3d Cir. 2005) ("Because Hollister failed to respond in any way to the USPS's second motion to dismiss, the District Court did not err in treating the UPSP's motion to dismiss as unopposed); *Person v. Teamster Local Union 863*, 2013 WL 5676802, at *2 (D.N.J. Oct. 17, 2013) ("Failure to raise legal arguments in opposition to a motion to dismiss results in waiver.").

The express warranty claim is therefore dismissed.

III. Conclusion

For the reasons set forth above, I will dismiss the Amended Complaint. The dismissal is without prejudice to the submission, within 30 days, of a proposed Second Amended Complaint. An appropriate order follows.

Dated: December 21, 2020

/s/ Kevin McNulty

Kevin McNulty
United States District Judge